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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 944,497	08/31/2001	Mohan Ramachandra Wani	A34628; 066123.0109	2639

21003 7590 03/25/2003

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EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/944,497

Applicant(s)
Ramachandra et al.

Examiner
Randall Winston

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1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above, claim(s) 1-8 and 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

Applicants' election with traverse of Group III, Claims 9-20 in Paper No. 5 is acknowledged. The traversal is on the grounds that the applicants argue that Groups III and IV are not sufficiently independent and distinct so as to require restriction in the present case. Applicants' argument is found persuasive, thus, Group III and IV will be rejoined. Furthermore, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement for Group I, II and V, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 9-30 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 19, 20, 21, 26, 27 are rendered vague and indefinite by the term "mussel hydrolysate" because this term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by-process since product-by-process claims are intended to define products which are otherwise difficult to define (and/or distinguish from the

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prior art). For example, is the mussel hydrolysate obtained via extraction with water, a polar solvent, a non-polar solvent, and acid or base, a squeezed extract, or something else? It is well accepted in the art that extraction with one of various distinct solvents, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the desired functional effect(s) instantly claimed and/or disclosed. Since the mussel hydrolysate itself is clearly essential to the claimed invention, the step(s) by which the claimed mussel hydrolysate is obtained are also clearly essential and, therefore, must be recited in the claim language itself(i.e., as a product-by-process). Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot read into the claims(see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention. Therefore, it is strongly suggested that applicant may overcome this rejection by clearly defining what type of an extract is an "extract of mussel hydrolysate from Indian green mussel" being utilized (please see, specification page 8-10 for product by process guidance).

Claims 9 and 21 are rendered vague and indefinite because they fail to recite any operative amount of the claimed mussel hydrolysate ingredient. Therefore, it is unclear if the mussel hydrolysate ingredient is an active agent within the composition, if it is merely some type of inert agent, and/or if it is present in very small amounts representing perhaps a contaminant or residue. The claimed mussel hydrolysate is deemed to be essential elements of the invention and,

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as such, they should be clearly defined (functionally) in the claim language itself. Accordingly, it is suggested that the phrase--biologically effective amounts-- be inserted after the word "comprising" (Claim 9 line 2 and claim 21 line 2) or, alternatively, that the limitations recited in claims 19 and 20 be appropriately incorporated into claim 9 and the limitations recited in claims 26 and 27 be appropriately incorporated into claim 21 to clarify this ambiguity.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

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CHRISTOPHER R. TATE
PRIMARY EXAMINER